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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,947	06/16/2000	Christine Icard-Liepkalns		2918

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	14

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/595,947	Applicant(s) ICARD-LIEPKALNS ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-10 cites SEQ ID NO:10 as the claimed nucleotide sequence, however, SEQ ID NO:10 is a peptide sequence, it appears the nucleotide sequence is SEQ ID NO:1. To advance prosecution, SEQ ID NO:1 is treated as the claimed nucleotide sequence.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-10, 19-30 and 39-46, drawn to a nucleic acid comprising a polynucleotide sequence of SEQ ID NO:1, or of a complementary polynucleotide sequence; a recombinant vector comprising the nucleic acid; a recombinant host cell comprising the nucleic acid; a pharmaceutical composition comprising the nucleic acid, the recombinant vector or the host cell; classified in class 536, subclass 23.5, class 435, subclasses 320.1 and 325.

II. Claims 11-14, drawn to a kit for amplifying the nucleic acid of claim 1, comprising two nucleotide primers, wherein the two nucleotide primers are selected from the group consisting of at least 15 consecutive nucleotides of SEQ ID NO:9 and one polynucleotide sequence of SEQ ID NOs:9, 11, 12, 14-19, 21, 23, 24 or 25, and reagents for an amplification reaction; and a method of amplifying a region of the nucleic acid of claim 1, classified in class 536, subclass 23.1.

Should Group II be elected, applicant is required to select two nucleotide primers from the nucleotide sequences in claim 14 (a) or claim 14 (b), each nucleotide primer is identified by a "SEQ ID NO:". Any nucleic acid is considered, absent factual data to the contrary, a distinct nucleotide. This is not a species election.

III. Claims 15-18, drawn to a kit for detecting the nucleic acid of claim 1, comprising a nucleotide probe; and a method of detecting the nucleic acid of claim 1, classified in class 536, subclass 23.1.

Should Group III be elected, applicant is required to select one nucleotide sequence identified by a "SEQ ID NO:" from claim 15 or 17. Any nucleic acid is considered, absent factual data to the contrary, a distinct nucleotide. This is not a species election.

IV. Claims 31, 34 and 47-48, drawn to polypeptide comprising an amino acid sequence of SEQ ID NO:10 and a pharmaceutical composition comprising the polypeptide, classified in class 530, subclass 350.

V. Claims 32, 33 and 35-38, drawn to an antibody directed against the polypeptide; a diagnostic kit for detecting a polypeptide comprising the antibody; and a method of detecting a polypeptide, classified in class 530, subclass 387.1.

VI. Claims 49-56, drawn to a use of the nucleic acid, the recombinant vector or recombinant host cell for the manufacture of medicament, classified in class 536, subclass 23.5, class 435, subclasses 320.1 and 325.

VII. Claims 57-58, drawn to a use of the polypeptide for the manufacture of medicament; classified in class 530, subclass 350.

VIII. Claim 59, drawn to a use of the recombinant host cell expressing the polypeptide for screening an active ingredient for the treatment of a nervous system dysfunction, classified in class 435, subclass 325.

IX. Claims 60-62, drawn to an implant comprising the recombinant host cell; classified in class 424, subclass 422, and 435, subclass 325.

X. Claims 63-65, drawn to a method of identifying a modulator, agonist or antagonist of the polypeptide, using the recombinant host cell to express the polypeptide, and measuring the β-galactosidase activity in the cell in the presence or absence of the modulator; classified in 536, subclass 23.5, class 435, subclasses 320.1 and 325.

XI. Claim 66, drawn to a use of the polypeptide to control or participate in the gene expression, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid, a protein and an antibody, which are patentably distinct each from the other because they are physically and functionally distinct chemical entities and also have different utilities. For example, protein can be used for studying receptor, nucleic acid can be used for making probes in northern or southern hybridization and an antibody can be used for western blotting.

The products of Inventions I, II, III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to nucleic acid, vector or host cell; a kit for amplifying the nucleic acid; a kit for detecting the nucleic acid; and an implant comprising recombinant host cells that would have different modes of operation and different utilities. For example, the nucleic acid of Invention I comprising SEQ ID NO:1, whereas Invention II would

contain different nucleotide sequences as nucleotide primers, Invention III would contain different nucleotide sequences as a nucleotide probe, and Invention IX would contain recombinant host cells as implant.

The product of Invention I and the methods of Inventions II, III, VI, VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions II, III, VI, VIII and X are alternative processes of the use of the product of Invention I.

The product of Invention IV and the methods of Inventions VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VII and XI are alternative processes of the use of the product of Invention IV.

The methods of Inventions II, III, V, VI, VII, VIII, X and XI are patentably distinct each from the other because they have different method steps, utilize different components and would produce different outcomes.

The products of Inventions IV and V are distinct from the methods of Inventions II, III, VI, VIII and X because the products of Inventions IV and V can be neither made by nor used in the methods of II, III, VI, VIII and X.

The products of Inventions I, II, III and IX are distinct from the methods of Inventions V, VII and XI because the products of Inventions I, II, III and IX can be neither made by nor used in the methods of V, VII and XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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August 21, 2002

GABRIELLE BUGAISKY
PRIMARY EXAMINER